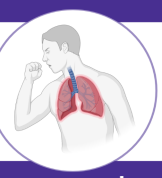
Results From a Phase 4, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study of Repository Corticotropin Injection for the Treatment of Pulmonary Sarcoidosis

Mirsaeidi M, Baughman RP, Sahoo D, Tarau E (2023) *Pulmonary Therapy*

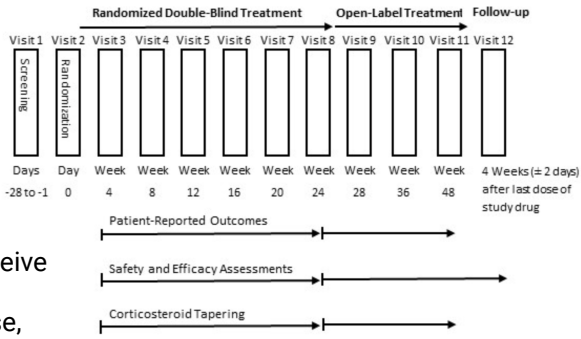


Pulmonary sarcoidosis is characterized by inflammation of the lungs

Standard treatments include **glucocorticoids**, which may have harmful **side effects**

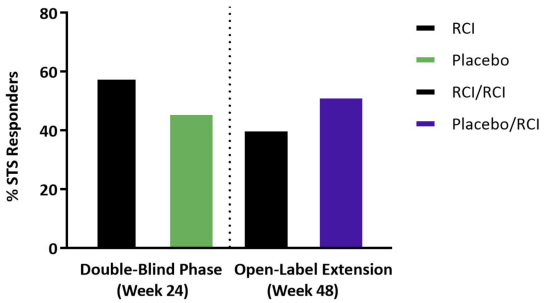
Is repository corticotropin injection (RCI, Acthar® Gel) safe and effective to treat pulmonary sarcoidosis in patients who do not adequately respond to glucocorticoids?

PULSAR was a multicenter, randomized, double-blind, 24-week study with an additional 24-week open-label extension

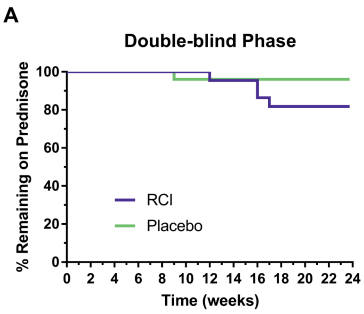


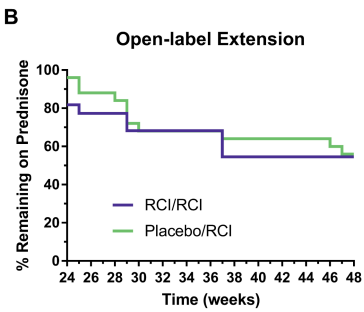
55 subjects were randomized to receive RCI (n=27) or placebo (n=28):
49 completed the double-blind phase,
47 continued into the open-label extension

Efficacy assessments showed trends of greater improvements with RCI compared with placebo in the double-blind phase, which were generally maintained through the open-label extension



RCI improved sarcoidosis treatment scores (STS)





Patients taking RCI discontinued glucocorticoid usage faster than those taking placebo

Other Key Findings

- Patients taking RCI reported less fatigue and displayed better general health
- RCI improved lung imaging by high-resolution computed tomography (HRCT) and chest x-rays
- Side effects for RCI were mostly mild or moderate with no new or unexpected safety concerns

Results suggest that RCI is a safe treatment for pulmonary sarcoidosis with trends demonstrating greater improvements when compared with placebo in patients receiving standard-of-care therapy

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